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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/036,645	03/06/98	BERD	D 1225/00675.U

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HM12/0224

EXAMINER

ARTHUR, L

ART UNIT

PAPER NUMBER

1634

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/036,645

Applicant(s)
Berd

Examiner
First Last

Group Art Unit
1234



☒ Responsive to communication(s) filed on Mar 6, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-20 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 1-3, 5, 7, 13, and 15 is/are allowed.

☒ Claim(s) 4, 6, 8-12, 14, and 16-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. This case is reissue application of patent 5,290,551. Original claims 1 and 2 have not been amended and claims 3-20 have been newly added. The current status of the pending claims is as follows:

- I. Claims 4,6,8-12,14 and 16-20 are rejected under 35 U.S.C. 251.
- II. Claims 4,6,8-12,14 and 16-20 are rejected under 35 U.S.C. 112, first paragraph.
- III. Claims 4, 10 and 18 are rejected under 35 U.S.C. 112, second paragraph.
- IV. Claims 1-3, 5,7,13 and 15 are allowable.

2. The amendment filed March 6, 1998, proposes amendments to (1) add new claims 3-20 without underlining the new subject matter (see MPEP 1453, especially 37 CFR 1.121(b)(2)(i)(c) and Example 5) that do not comply with 37 CFR 1.121(b), which sets forth the manner of making amendments in reissue applications. Applicant should also note that it is not necessary to present original patent claims 1 and 2 in the preliminary amendment if no amendments of these claims is desired. Original claims should appear as part of the cut-up copy of the original patent. A supplemental paper correctly amending the reissue application is required.

3. Claims 4,6,8-12,14,16-20 are rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is as follows:

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A. The patent does not provide support for the vaccine comprising cells irradiated with “a low radiation dose”, as recited in instant claims 4,10 and 18, because the patent only describes cells irradiated with 2500 R. Although 2500 R is recognized as a low radiation dose, this statement is not equivalent to a statement that 2500 R was used as an example of a low dose of radiation. The scope of the term “low radiation dose” is significantly broader than the specific radiation dose of 2500 R disclosed in the patent and the patent has not set forth the concept that any low dose of radiation was part of the original concept of the invention.

B. The patent also does not provide support for the concept that the vaccine is injected “at multiple sites per administration”, as recited in instant claims 6 and 14, or “more than two intradermal administrations”, as recited instant claims 11-12 and 19-20, because the patent only describes injection of the vaccine “into 3 contiguous sites on the upper arms or legs”. This statement is not support for the concept that the vaccine is injected at multiple sites per administration because “multiple” is not limited to being “three” and “sites” is not limited to being “arms or legs”. The patent contains no statement or suggestion that the specific description teaching how to administer the vaccine is one example or embodiment of the broader concept that the vaccine can actually be administered at less than or more than 3 sites wherein the sites can be other than arms and legs.

C. The patent does not support the concept that the vaccine is administered specifically to post-surgical melanoma patients, as recited in instant claims 8 and 16. The amendment points to column 5, lines 43-44 as providing support for this amendment. However, the paragraph of the

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patent containing this sentence is brief description of results obtained after treatment with the vaccine and is a comparison of excised tumors in three cases before and after immunotherapy. This teaching does not at all address the concept of post surgical administration of the claimed vaccine.

D. The patent does not provide support for that administration of the vaccine to “stage four melanoma patients”, as recited in instant claims 9 and 17, because there is not specific teaching that this particular group of patients was targeted. The amendment points to column 5, lines 4-6, as providing support on the basis that the patent teaches that tumor regression occurred in lung and liver metastases which were known in the art only to occur in stage four melanoma patients. This teaching does not provide adequate support for the amendment because the patent does not teach the concept of specifically administering the vaccine to patients with stage four melanoma. The patent is describing the results of vaccine administration on tumor regression including tumors in skin and nodule metastases and also in lung and liver metastases. While it may be true that lung and liver metastases were known to occur in stage four melanoma, the patent is not clear that the vaccine was administered when or after these patients were characterized as having stage four melanoma.

E. The patent does not support the method comprising “more than two intradermal administrations” because the patent only teaches that the vaccine is “reinject every 4 weeks and an example in which the vaccine was administered three times. Nowhere does the patent teach that the vaccine was to be administered four or more times and that the vaccine could be

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administered at any intradermal site. Instead the patent teaches that the vaccine was to be administered at three contiguous sites on the arms or legs. This amendment has broadened the scope of the claimed invention to include subject matter which was not described as being part of the original concept of the invention.

4. Claims 4,6,8-12,14,16-20 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide support for the vaccine comprising cells irradiated with "a low radiation dose" because the patent only describes cells irradiated with 2500 R. Although 2500 R is recognized as a low radiation dose, this statement is not equivalent to a statement that 2500 R was used as an example of a low dose of radiation. The scope of the term "low radiation dose" is significantly broader than the specific radiation dose of 2500 R and the specification has not set forth the concept that any low dose of radiation was part of the original concept of the invention.

B. The specification also does not provide support for the concept that the vaccine is injected "at multiple sites per administration" or "more than two intradermal injections" because the patent only describes injection of the vaccine "into 3 contiguous sites on the upper arms or legs". This statement is not support for the concept that the vaccine is injected at multiple sites

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per administration because “multiple” is not limited to being “three” and “sites” is not limited to being “arms or legs”. The specification contains no statement or suggestion that the specific description teaching how to administer the vaccine is one example or embodiment of the broader concept that the vaccine can actually be administered at less than or more than 3 sites wherein the sites can be other than arms and legs.

C. The specification does not support the concept that the vaccine is administered specifically to post-surgical melanoma patients. The amendment points to column 5, lines 43-44 as providing support for this amendment. However, the paragraph of the specification containing this sentence is brief description of results obtained after treatment with the vaccine and is a comparison of excised tumors in three cases before and after immunotherapy. This teaching does not at all address the concept of post surgical administration of the claimed vaccine.

D. The specification does not provide support for that administration of the vaccine to “stage four melanoma patients” because there is not specific teaching that this particular group of patients was targeted. The amendment points to column 5, lines 4-6, as providing support on the basis that the patent teaches that tumor regression occurred in lung and liver metastases which were known in the art only to occur in stage four melanoma patients. This teaching does not provide adequate support for the amendment because the patent does not teach the concept of specifically administering the vaccine to patients with stage four melanoma. The specification is describing the results of vaccine administration on tumor regression including tumors in skin and nodule metastases and also in lung and liver metastases. While it may be true that lung and liver

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metastases were known to occur in stage four melanoma, the specification is not clear that the vaccine was administered when or after these patients were characterized as having stage four melanoma.

E. The specification does not support the method comprising “more than two intradermal administrations” because the patent only teaches that the vaccine is “reinjecting every 4 weeks and an example in which the vaccine was administered three times. Nowhere does the specification teach that the vaccine was to be administered four or more times and that the vaccine could be administered at any intradermal site. Instead the specification teaches that the vaccine was to be administered at three contiguous sites on the arms or legs. This amendment has broadened the scope of the claimed invention to include subject matter which was not described as being part of the original concept of the invention.

5. Claims 4,10,18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4,10 and 18 are indefinite over the recitation of “low radiation dose” because the specification contains no definition of the term and consequently the skilled artisan would have no way of determining the metes and bounds of the claims with regard to the limits of radiation doses considered to be “low”. The specification has only described one specific radiation dose, i.e. 2500 R.

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6. With regard to the belief that the inventor may have claimed more than he had a right to claim on the basis of the abstract published March 1989, this reference was previously considered in during prosecution of application 07/985,334 but was determined to be a "non-enabling" reference. Although the abstract describes the vaccine claimed in claims 1 and the method of claim 2, the abstract did not enable the use of the vaccine because the abstract only teaches that one patient developed erythema and swelling around the tumors and some tumor regression, a second patient showed erythema and swelling with no regression and a third patient exhibited some erythema. These results were not considered to overcome the high degree of unpredictability in the success of the claimed vaccine and consequently this reference was not used as prior art against the claims. Instead the claims were rejected under 35 U.S.C. 101 and under 35 U.S.C. 112, first paragraph, as not being enabled. These rejection were overcome by the filing of four Rule 132 Declarations (one filed March 6, 1992, one filed October 5, 1992 and two filed June 25, 1993) which provided sufficient data to support the reasonable predictability of a beneficial effect from treatment with this vaccine. Therefore, it is concluded that the inventor did not in fact claim more than he had a right to on the basis of the Berd et al. abstract published March 1989.

7. The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

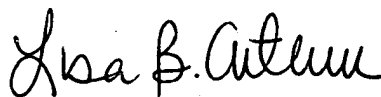
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8. Claims 1,2, 3,5,7,13 and 15 are allowable over the prior art because the Berd et al. abstract (discussed in above in paragraph 6) was not an enabling reference which provided the ordinary artisan with a reasonable expectation of success for making and using the described vaccine and melanoma treatment method. The newly added claims 3,5,7,13,15 include additional limitations to the allowable vaccine composition of claim 1 and the method of claim 2 which were described and supported in the original patent, namely, that the autologous melanoma cells were cryopreserved and that the vaccine is injected into three sites on an arm or a leg. Therefore, these claims are also allowable.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa Arthur whose telephone number is (703) 308-3988. The examiner can normally be reached on Monday-Wednesday from 7:00AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


LISA B. ARTHUR
PRIMARY EXAMINER
GROUP 1800

February 17, 1999